PHS PATENT LICENSE AGREEMENT-NONEXCLUSIVE

For Office of Technology Transfer/NIH internal use only:

Patent License Number:_____

Serial Numbers of Licensed Patents:
_____

Licensee: _____

CRADA Number (if applicable): _____

Additional Remarks:
_____

_____

_____

_____

Public Health Service

PATENT LICENSE AGREEMENT-NONEXCLUSIVE

This Patent License Agreement, hereinafter referred to as the "Agreement," consists of this Cover Page, an attached agreement, a Signature Page, Appendix A (Patent or Patent Application), Appendix B (Fields of Use and Territory), Appendix C (Royalties), and Appendix D (Modifications). This Cover Page serves to identify the Parties to this Agreement as follows:

1. The National Institutes of Health ("NIH") or the Centers for Disease Control ("CDC"), hereinafter singly or collectively referred to as "PHS," agencies of the United States Public Health Service within the Department of Health and Human Services ("DHHS"); and

2. The person, corporation, or institution identified above and/or on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "Licensee."

PHS and Licensee agree as follows:

1. BACKGROUND

1.01 In the course of conducting biomedical and behavioral research, PHS investigators made inventions that may have commercial applicability.

1.02 By assignment of rights from PHS employees and other inventors, DHHS, on behalf of the United States Government, owns intellectual property rights claimed in any United States and foreign patent applications or patents corresponding to the assigned inventions. DHHS also owns any tangible embodiments of these inventions actually reduced to practice by PHS.

1.03 The Assistant Secretary for Health of DHHS has delegated to PHS the authority to enter into this Agreement for the licensing of the rights to these inventions under 35 USC §§200-212, the Federal Technology Transfer Act of 1986, 15 USC §3710a, and/or the regulations governing the licensing of Government-owned inventions, 37 CFR Part 404.

1.04 PHS desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.05 Licensee desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.01 "Licensed Patent Rights" shall mean:

a) US patent applications and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents;

b) to the extent that the following contain one or more claims directed to the invention or inventions claimed in a) above: i) continuations-in-part of a) above; ii) all divisions and continuations of these continuations-in-part; iii) all patents issuing from such continuations-in-part, divisions, and continuations; and iv) any reissues, reexaminations, and extensions of all such patents;

c) to the extent that the following contain one or more claims directed to the invention or inventions claimed in a) above: all counterpart foreign applications and patents to a) and b) above, including those listed in Appendix A. Licensed Patent Rights shall not include b) or c) above to the extent that they contain one or more claims directed to new matter which is not the subject matter of a claim in a) above.

2.02 "Licensed Product(s)" means tangible materials which, in the course of manufacture, use, or sale would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.03 "Licensed Process(es)" means processes which, in the course of being practiced would, in the absence of this Agreement, infringe one or more claims of the Licensed Patent Rights that have not been held invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.04 "Licensed Territory" means the geographical area identified in Appendix B.

2.05 "Net Sales" means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of Licensee and from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances actually granted, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by Licensee and on its payroll, or for the cost of collections.

2.06 "First Commercial Sale" means the initial transfer by or on behalf of Licensee of Licensed Products or the initial practice of a Licensed Process in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.

2.07 "Government" means the government of the United States of America. 2.08 "Licensed Fields of Use" means the fields of use identified in Appendix B.

3. GRANT OF RIGHTS

3.01 PHS hereby grants and Licensee accepts, subject to the terms and conditions of this Agreement, a nonexclusive license to Licensee under the Licensed Patent Rights in the Licensed Territory to make and have made, to use and have used, and to sell and have sold any Licensed Products in the Licensed Fields of Use and to practice and have practiced any Licensed Processes in the Licensed Fields of Use.

3.02 Licensee has no right to grant sublicenses.

3.03 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of PHS other than the Licensed Patent Rights regardless of whether such patents are dominant or subordinate to Licensed Patent Rights.

4. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

4.01 Licensee agrees that products used or sold in the united states embodying Licensed Products or produced through use of Licensed Processes shall be manufactured substantially in the united states, unless a written waiver is obtained in advance from PHS.

5. ROYALTIES AND REIMBURSEMENT

5.01 Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty as set forth in Appendix C within thirty (30) days from the date that this Agreement becomes effective.

5.02 Licensee agrees to pay to PHS a nonrefundable minimum annual royalty as set forth in Appendix C. The minimum annual royalty is due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year. The minimum annual royalty for the first calendar year of this Agreement is due and payable within thirty (30) days from the effective date of this Agreement and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1.

5.03 Licensee agrees to pay PHS benchmark royalties as set forth in Appendix C.

5.04 Licensee agrees to pay PHS earned royalties as set forth in Appendix C.

5.05 A claim of a patent licensed under this Agreement shall cease to fall within the Licensed Patent Rights for the purpose of computing the minimum annual royalty and earned royalty payments in any given country on the earliest of the dates that a) the claim has been abandoned but not continued, b) the patent expires, c) the patent is no longer maintained by the Government, or d) all claims of the Licensed Patent Rights have been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

5.06 No multiple royalties shall be payable because any Licensed Products or Licensed Processes are covered by more than one of the Licensed Patent Rights.

5.07 On sales of Licensed Products by Licensee in other than an arm's-length transaction, the value of the Net Sales attributed under this Article 5 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.

5.08 As an additional royalty, Licensee agrees to pay PHS, within (60) days of PHS' submission of a statement and request for payment, an amount equivalent to all patent expenses previously incurred by PHS in the preparation, filing, prosecution, and maintenance of Licensed Patent Rights, to be divided equally among all nonexclusive commercialization licensees of record as of the date the statement and request for payment is sent by PHS to Licensee. Licensee further agrees to pay PHS annually, within sixty (60) days of PHS's submission of a statement and request for payment, a royalty amount equivalent to all such future patent expenses incurred during the previous calendar year divided equally among all nonexclusive commercialization licensees of record as of the date the statement and request for payment are sent by PHS to Licensee. Fifty percent (50%) of the cumulative amount of the payments due under this Paragraph may be credited against royalties due under Paragraph 5.03; however, the net royalty payment in any calendar year may not be lower than the minimum annual royalty specified in Appendix C. Licensee may elect to surrender its rights in any country of the Licensed Territory under any Licensed Patent Rights upon sixty (60) days' written notice to PHS and owe no payment obligation under this Paragraph for subsequent patent-related expenses incurred in that country.

6. RECORD KEEPING

6.01 Licensee agrees to keep accurate and correct records of Licensed Products made, used, or sold and Licensed Processes practiced under this Agreement appropriate to determine the amount of royalties due PHS. Such records shall be retained for at least five (5) years following a given reporting period. They shall be available during normal business hours for inspection at the expense of PHS by an accountant or other designated auditor selected by PHS for the sole purpose of verifying reports and payments

hereunder. The accountant or auditor shall only disclose to PHS information relating to the accuracy of reports and payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then Licensee shall reimburse PHS for the cost of the inspection at the time Licensee pays the unreported royalties, including any late charges as required by Paragraph 7.06 of this Agreement. All payments required under this Paragraph shall be due within thirty (30) days of the date PHS provides Licensee notice of the payment due.

7. REPORTS ON PROGRESS, SALES, AND PAYMENTS

7.01 Prior to signing this Agreement, Licensee has provided to PHS a written commercialization plan ("Commercial Development Plan") under which Licensee intends to bring the subject matter of the Licensed Patent Rights into commercial use. The Commercial Development Plan is hereby incorporated by reference into this Agreement.

7.02 Licensee shall provide written annual reports on its product development progress or efforts to commercialize under the Commercial Development Plan for each of the Licensed Fields of Use within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, marketing, and sales during the preceding calendar year, as well as plans for the present calendar year. Licensee agrees to provide any additional data reasonably required by PHS to evaluate Licensee's performance.

7.03 Licensee shall report to PHS the date of the First Commercial Sale in each country in the Licensed Territory within thirty (30) days of such occurrence.

7.04 Licensee shall submit to PHS within sixty (60) days after each calendar half-year ending June 30 and December 31 a royalty report setting forth for the preceding half-year period the amount of the Licensed Products sold or Licensed Processes practiced by or on behalf of Licensee in each country within the Licensed Territory, the Net Sales, and the amount of royalty accordingly due. With each such royalty report, Licensee shall submit payment of the earned royalties due. If no earned royalties are due to PHS for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of Licensee and shall include a detailed listing of all deductions made under Paragraph 2.05 to determine Net Sales made under Article 5 to determine royalties due.

7.05 Royalties due under Article 5 shall be paid in US dollars. For conversion of foreign currency to US dollars, the conversion rate shall be the rate quoted in The Wall Street Journal on the day that the payment is due. All checks and bank drafts shall be drawn on United States banks and shall be payable to NIH/Patent Licensing at the address shown on the "Signature Page" below. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to US dollars shall be paid entirely by Licensee.

All royalty payments due under this Agreement shall be mailed to the following address: NIH, PO Box 360120, Pittsburgh, Pennsylvania 15251-6120. The royalty report required by paragraph 7.04 of this Agreement shall accompany each such payment and a copy of such report shall also be mailed to PHS at its address for notices indicated on the "Signature Page" of this Agreement.

7.6 Late charges will be applied to any overdue payments as required by the US Department of Treasury in the Treasury Fiscal Requirements Manual, Section 8025.40. The payment of such late charges shall not prevent PHS from exercising any other rights it may have as a consequence of the lateness of any payment.

7.07 All plans and reports required by this Article 7 and marked "confidential" by Licensee shall be treated by PHS as commercial and financial information obtained from a person, and as privileged and confidential and, to the extent permitted by law, shall not be subject to disclosure under the Freedom of Information Act, 5 USC §552.

8. PERFORMANCE

8.01 Licensee shall use its reasonable best efforts to introduce the Licensed Products into the commercial market or apply the Licensed Processes to commercial use as soon as practicable. "Reasonable best efforts" for the purpose of this provision shall include, but not be limited to, adherence to the Commercial Development Plan.

8.02 Upon the First Commercial Sale, until the expiration of this Agreement, Licensee shall use its reasonable best efforts to keep Licensed Products and Licensed Processes reasonably accessible to the public.

9. INFRINGEMENT AND PATENT ENFORCEMENT

9.01 PHS and Licensee agree to notify each other promptly of each infringement or possible infringement, as well as any facts which may affect the validity, scope, or enforceability of the Licensed Patent Rights of which either Party becomes aware.

9.02 If PHS has been unable to eliminate a substantial infringement within one (1) year of written notification to the Office of Technology Transfer from Licensee of the existence of a substantial infringement and has not instituted infringement litigation, Licensee shall be excused from the payment of the minimum annual royalty and earned royalties in any country in which the substantial infringement continues to occur. Thereafter, when the substantial infringement has ceased or an infringement suit has been initiated, PHS shall so notify the Licensee in writing, at which time Licensee's obligation to pay such royalties shall resume as of the date of such notification.

9.03 In the event that a declaratory judgment action alleging invalidity of any of the Licensed Patent Rights shall be brought against PHS, PHS agrees to notify Licensee that an action alleging invalidity has been brought. PHS does not represent that it will commence legal action to defend against a declaratory action alleging invalidity. Licensee shall take no action to compel the Government either to initiate or to join in any such declaratory judgment action. Should the Government be made a party to any such suit by motion or any other action of Licensee, Licensee shall reimburse the Government for any costs, expenses, or fees which the Government incurs as a result of its defending against such motion or other action taken in response to the motion. Upon Licensee's payment of all costs incurred by the Government as a result of Licensee's joinder motion or other action, these actions by Licensee will not be considered a default in the performance of any material obligation under this Agreement.

10. NEGATION OF WARRANTIES AND INDEMNIFICATION

10.01 PHS offers no warranties other than those specified in Article 1.

10.02 PHS does not warrant the validity of the Licensed Patent Rights and makes no representations whatsoever with regard to the scope of the Licensed Patent Rights, or that the Licensed Patent Rights may be exploited without infringing other patents or other intellectual property rights of third parties.

10.03 PHS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS.

10.04 PHS does not represent that it will commence legal actions against third parties infringing the Licensed Patent Rights.

10.05 Licensee shall indemnify and hold PHS, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of a) the use by or on behalf of Licensee or its directors, employees, or third parties of any Licensed Patent Rights, or b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes, or other products or processes developed in connection with or arising out of the Licensed Patent Rights. Licensee agrees to maintain a liability insurance program consistent with sound business practice.

11. TERMINATION AND MODIFICATION OF RIGHTS

11.01 This Agreement is effective when signed by all parties and shall extend to the expiration of the last to expire of the Licensed Patent Rights unless sooner terminated as provided in this Article 11.

11.02 In the event that Licensee is in default in the performance of any material obligations under this Agreement, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, PHS may terminate this Agreement by written notice.

11.03 At least thirty (30) days prior to filing a petition in bankruptcy, Licensee must inform PHS in writing of its intention to file the petition in bankruptcy or of a third party's intention to file an involuntary petition in bankruptcy.

11.04 In the event that Licensee becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, Licensee shall immediately notify PHS in writing. Furthermore, PHS shall have the right to terminate this Agreement by giving Licensee written notice. Termination of this Agreement is effective upon Licensee's receipt of the written notice.

11.05 Licensee shall have a unilateral right to terminate this Agreement and/or its rights in any country by giving PHS sixty (60) days' written notice to that effect.

11.06 PHS shall specifically have the right to terminate or modify, at its option, this Agreement, if PHS determines that the Licensee:

1) is not executing the Commercial Development Plan submitted with its request for a license and the Licensee cannot otherwise demonstrate to PHS's satisfaction that the Licensee has taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the Licensed Products or Licensed Processes;

2) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by the license agreement;

3) has committed a substantial breach of a covenant or agreement contained in the license;

4) is not keeping Licensed Products or Licensed Processes reasonably available to the public after commercial use commences;

5) cannot reasonably satisfy unmet health and safety needs; or

6) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 4.01 unless waived.

In making this determination, PHS will take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by Licensee under Paragraph 7.02. Prior to invoking this right, PHS shall give written notice to Licensee providing Licensee specific notice of, and a ninety (90) day opportunity to respond to, PHS's concerns as to the previous items 1) to 6). If Licensee fails to alleviate PHS's concerns as to the previous items 1) to 6) or fails to initiate corrective action to PHS's satisfaction, PHS may terminate this Agreement.

11.07 PHS reserves the right according to 35 USC §209(f)(4) to terminate or modify this Agreement if it is determined that such action is necessary to meet requirements for public use specified by Federal regulations issued after the date of the license and such requirements are not reasonably satisfied by Licensee.

11.08 Within thirty (30) days of receipt of written notice of PHS's unilateral decision to terminate this Agreement, Licensee may, consistent with the provisions of 37 CFR §404.11, appeal the decision by written submission to the Director of NIH or designee. The decision of the NIH Director or designee shall be the final agency decision. Licensee may thereafter exercise any and all administrative or judicial remedies that may be available.

11.09 Within ninety (90) days of termination of this Agreement under this Article 11 or expiration under Paragraph 11.01, a final report shall be submitted by Licensee. Any royalty payments and unreimbursed patent expenses due to PHS become immediately due and payable upon termination or expiration of this Agreement, and Licensee shall return all Licensed Products or other materials included within the Licensed Patent Rights to PHS or provide PHS with certification of their destruction.

Paragraphs 6.01, 7.05-7.07, 10.01, 10.03, 10.05, and 11.08 of this Agreement shall survive termination of this Agreement.

12. GENERAL PROVISIONS

12.01 Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of the Government to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right by the Government or excuse a similar subsequent failure to perform any such term or condition by Licensee.

12.02 This Agreement constitutes the entire agreement between the Parties relating to the subject matter of the Licensed Patent Rights, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this Agreement.

12.03 The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such determination shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

12.04 If either Party desires a modification to this Agreement, the Parties shall, upon reasonable notice of the proposed modification by the Party desiring the change, confer in good faith to determine the desirability of such modification. No modification will be effective until a written amendment is signed by the signatories to this Agreement or their designees.

12.05 The construction, validity, performance, and effect of this Agreement shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

12.06 All notices required or permitted by this Agreement shall be given by prepaid, first class, registered or certified mail properly addressed to the other Party at the address designated on the following Signature Page, or to such other address as may be designated in writing by such other Party, and shall be effective as of the date of the postmark of such notice.

12.07 This Agreement shall not be assigned by Licensee except a) with the prior written consent of PHS; or b) as part of a sale or transfer of substantially the entire business of Licensee relating to operations which concern this Agreement. Licensee shall notify PHS within ten (10) days of any assignment of this Agreement by Licensee.

12.08 Licensee agrees in its use of any PHS-supplied materials to comply with all applicable statutes, regulations, and guidelines, including Public Health Service and National Institutes of Health regulations and guidelines. Licensee agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. Licensee agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying PHS, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to PHS of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

12.09 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant agency of the US Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. PHS neither represents that a license is or is not required or that, if required, it shall be issued.

12.10 Licensee agrees to mark the Licensed Products or their packaging sold in the United States with all applicable US patent numbers and similarly to indicate "Patent Pending" status. All Licensed Products manufactured in, shipped to, or sold in other countries shall be marked in such a manner as to preserve PHS patent rights in such countries.

12.11 By entering into this Agreement, PHS does not directly or indirectly endorse any product or service provided, or to be provided, by Licensee whether directly or indirectly related to this Agreement. Licensee shall not state or imply that this Agreement is an endorsement by the Government, PHS, any other Government organizational unit, or any Government employee. Additionally, Licensee shall not use the names of PHS, NIH, or CDC or their employees in any advertising, promotional, or sales literature without the prior written consent of PHS.

12.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this Agreement or a breach of this Agreement, except for appeals of modification or termination decisions provided for in Article 11. Licensee agrees first to appeal any such unsettled claims or controversies to the Director of NIH, or designee, whose decision shall be considered the final agency decision. Thereafter, Licensee may exercise any administrative or judicial remedies that may be available.

12.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

SIGNATURE PAGE

FOR PHS:

_____ Date: _____
Barbara McGarey, JD
Deputy Director
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices: Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892

FOR Licensee:

(Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of Licensee made or referred to in this document are truthful and accurate.):

_____
Name of Licensee

_____ Date _____
Signature of Authorized Official
Printed Name and Title _____

Mailing Address for Notices:
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_____

_____

_____

APPENDIX A-Patent or Patent Application

APPENDIX B-Licensed Fields of Use and Territory

APPENDIX C-Royalties

ROYALTIES:

Licensee agrees to pay to PHS a noncreditable, nonrefundable license issue royalty in the amount of _____.

Licensee agrees to pay to PHS a nonrefundable minimum annual royalty in the amount of _____.

Licensee agrees to pay PHS earned royalties on Net Sales as follows:

Licensee agrees to pay PHS benchmark royalties as follows:

APPENDIX D-Modifications

PHS and Licensee agree to the following modifications to the Articles and Paragraphs of this Agreement: